DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Insulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of an injectable suspension of zinc insulin of porcine origin for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed NADA 141–236 for the veterinary prescription use of VETSULIN (porcine zinc insulin) Suspension for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus. The NADA is approved as of April 1, 2004, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.1160 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning April 1, 2004.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.1160 is added to read as follows:

§ 522.1160 Insulin.

(a) *Specifications*. Each milliliter of porcine zinc insulin suspension contains 40 international units (IU) of insulin.

(b) *Sponsor*. See No. 057926 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. (i) Administer by subcutaneous injection. An initial once-daily dose, administered by subcutaneous injection concurrently with or right after a meal, is calculated as follows:

Body Weight	Initial Dose
<10 kg[1] (<22 lb[2])	1 IU/kg + 1 IU
10 to 11 kg (22 to 24 lb)	1 IU/kg + 2 IU
12 to 20 kg (25 to 44 lb)	1 IU/kg + 3 IU
>20 kg (>44 lb)	1 IU/kg + 4 IU

[1] kg means kilograms.
[2] lb means pounds.

(ii) Adjust the once-daily dose described in paragraph (c)(1)(i) of this section at appropriate intervals based on clinical signs, urinalysis results, and glucose curve/spot check values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(2) *Indications for use*. For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 23, 2004.

Catherine P. Beck,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S